Traditional 510(k) Summary

FEB 11 2014

1. **Date Prepared:** January 16, 2014

2. **Applicant**

Amendia, Inc.
1755 West Oak Parkway
Marietta, GA 30062

3. **Application Correspondent**

Kapstone Medical, LLC
100 E. South Main St.
PO Box 1458
Waxhaw, NC 28173

Contact Person: John Kapitan, President
Tel: (704) 843-7852
Fax: (704) 831-5316
E-mail: jkapitan@kapstonemedical.com

4. **Device Name**

Trade Name:	Savannah-T® Pedicle Screw System
Classification Name:	Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
Regulation Number:	21 CFR 888.3070
Regulation Name:	Pedicle screw spinal system
Regulation Class:	III
Product Code:	NKB, MNI, MNH
Panel:	Orthopedic

5. **Predicate Device**

The Savannah-T® Pedicle Screw System is substantially equivalent to the following device:

K072116, Savannah Lumbar Percutaneous Stabilization System (SLPSS)

6. **Description of the Device**

The Savannah-T® Pedicle Screw System consists of pedicle screws, mono-axial and poly-axial screw heads, connecting rods, set screws, and transverse crossmembers, called the Savannah-Link. The screws are available in various diameters and lengths, and the rods are available in straight and curved versions in various lengths. The components are manufactured from Ti-6Al-4V (ASTM F136) and are provided non-sterile for single-use.

7. Indications for Use

The Savannah-T® is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine, specifically as follows:

- When intended for pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients the Savannah-T® is indicated for one or more of the following: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and/or failed previous fusion (pseudarthrosis).
- In addition, when used as a pedicle screw fixation system, the Savannah-T® is indicated for skeletally mature patients having degenerative spondylolisthesis with objective evidence of neurologic impairment and/or severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and who are having the device removed after the development of a solid fusion mass.

8. Summary of Performance Data

To characterize the strength of the Savannah-T®, the following testing was performed:

- static compression bending, static torsion, and dynamic compression bending in accordance with ASTM F1717-12

Results of these tests showed the Savannah-T® to be better or equivalent to the predicate device.

9. Substantial Equivalence

The Savannah-T® Pedicle Screw system is substantially equivalent to the predicate device, the Savannah Lumbar Percutaneous Stabilization System (SLPSS) (K072116). Both devices have the same "Indications for Use," are available by prescription only, and are provided non-sterile for single-use only. The Savannah-T® differs from the SLPSS in that the Savannah-T® includes additional screw heads, screw, and transverse crossmember, called the Savannah-Link. These differences do not negatively impact the overall safety and effectiveness of the device, and this was verified via mechanical testing. Therefore, it can be concluded that the Savannah-T® is both a safe and effective device and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

Amendia, Incorporated
% Kapstone Medical, LLC
Mr. John Kapitan
100 East South Main Street
P.O. Box 1458
Waxhaw, North Carolina 28173

Re: K132925
Trade/Device Name: Savannah-T® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III, or Unclassified
Product Code: NKB, MNH, MNI
Dated: January 16, 2014
Received: January 24, 2014

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: Savannah-T® Pedicle Screw System

Indications for Use:

The Savannah-T® is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine, specifically as follows:

- When intended for pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients the Savannah-T® is indicated for one or more of the following: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and/or failed previous fusion (pseudarthrosis).
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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132925